

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

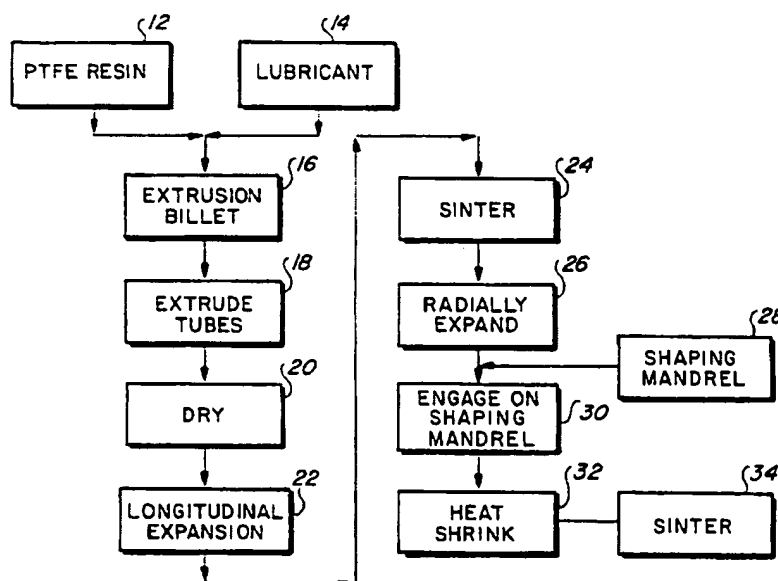
**THIS PAGE BLANK (USPTO)**



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification <sup>6</sup> : B29C 61/02, 55/26, A61F 2/06	A1	(11) International Publication Number: <b>WO 98/33638</b> (43) International Publication Date: 6 August 1998 (06.08.98)
(21) International Application Number: PCT/US98/02142 (22) International Filing Date: 2 February 1998 (02.02.98)  (30) Priority Data: 08/792.780                      3 February 1997 (03.02.97)                      US  (71) Applicant: IMPRA, INC. [US/US]; 1625 West Third Street, P.O. Box 1740, Tempe, AZ 85280-1740 (US).  (74) Agent: ROSENBAUM, David, G.; Sonnenschein, Nath & Rosenthal, 8000 Sears Tower, 233 South Wacker Drive, Chicago, IL 60606 (US).		(81) Designated States: AU, CA, JP, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).  <b>Published</b> <i>With international search report.          Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i>

(54) Title: METHOD OF MAKING EXPANDED POLYTETRAFLUOROETHYLENE PRODUCTS



## (57) Abstract

A method of shaping three-dimensional products by manipulating an expanded polytetrafluoroethylene tubular body into a desired three-dimensional conformation. The present invention entails radially expanding a longitudinally expanded polytetrafluoroethylene (ePTFE) tube (48) to form a radially expanded ePTFE (rePTFE) tube, engaging the rePTFE tube circumferentially about a shaping mandrel (50, 70, 140), heating the assembly to a temperature below the crystalline melt point temperature, or sintering temperature, of polytetrafluoroethylene to radially shrink the diameter of the rePTFE tube into intimate contact with the shaping mandrel, and heating the assembly to a temperature above the crystalline melt point temperature of polytetrafluoroethylene to amorphously lock the microstructure of the shaped polytetrafluoroethylene body.

**FOR THE PURPOSES OF INFORMATION ONLY**

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

## METHOD OF MAKING EXPANDED POLYTETRAFLUOROETHYLENE PRODUCTS

### Reference to Related Applications

This application is related to co-pending, commonly assigned PCT International  
5 Application Serial No. PCT/US96/02715, filed February 28, 1996, entitled "Apparatus and  
Method for Making Flanged End-to-Side Anastomosis."

### Background of the Invention

The present invention relates generally to methods of making shaped three-dimensional  
products from microporous expanded polytetrafluoroethylene. More particularly, the present  
10 invention relates to a method of shaping three-dimensional products by manipulating an  
expanded polytetrafluoroethylene tubular body into a desired three-dimensional conformation.  
The present invention entails radially expanding a longitudinally expanded  
polytetrafluoroethylene (ePTFE) tube to form a radially expanded ePTFE (rePTFE) tube,  
engaging the rePTFE tube circumferentially about a shaping mandrel, heating the assembly to  
15 a temperature below the crystalline melt point temperature, or sintering temperature, of  
polytetrafluoroethylene to radially shrink the diameter of the rePTFE tube into intimate contact  
with the shaping mandrel, and heating the assembly to a temperature above the crystalline melt  
point temperature of polytetrafluoroethylene to amorphously lock the microstructure of the  
shaped polytetrafluoroethylene body.

20 The three-dimensional shaped microporous expanded polytetrafluoroethylene products  
made in accordance with the method of the present invention are particularly well suited for use  
as medical implants, and are particularly useful as venous or arterial prostheses either as vein

or artery replacements, as endovascular liners, arterio-venous shunts, or as venous access grafts. As arterial or venous prosthesis, shaped microporous expanded polytetrafluoroethylene grafts have been made which have a flanged cuff section contiguous with an elongate tubular section. The cuffed prosthesis are particularly well suited for use in end-to-side anastomoses  
5 such as that required in femoro-popliteal bypass procedures where the flanged cuff section is sutured about an open arteriotomy to form the end-to-side anastomosis. As endovascular liners, the shaped expanded polytetrafluoroethylene products may be configured to have a taper along its longitudinal axis, with a proximal end having either a larger or smaller inner diameter than the distal end, or may have a step taper, where there is a tapered transition zone between  
10 two different inner diameter sections, or the product may be configured to have an intermediate section of a larger diameter than proximal or distal ends of the product, or the product may be configured into a bifurcated or trifurcated graft where each of the legs is formed from appropriately sized appendage sections of a base tubular graft member.

### **Background of the Prior Art**

15 Conventional processes for making ePTFE products are typically limited to fabricating sheets, tubes, rods or filaments. Methods for making complex conformational shapes of ePTFE are unknown in the prior art. The prior art is limited in its teaching to methods of making heat shrinkable tubing of either fluoroethylene co-polymers (FEP) or of non-expanded polytetrafluoroethylene (nPTFE). However, the uses of FEP and nPTFE heat shrink tubes has  
20 been limited to tubular profiles. Conventional methodologies are represented, for example, by Ely, Jr., *et al.* U.S. Patent No. 3,196,194 issued in 1965, which discloses a FEP-Fluorocarbon Heat Shrinkable Tubing which is first expanded 33 to 100 percent of the initial internal diameter and is then correspondingly heat shrinkable by a factor of 33 to 100 percent diameter at 250 -

400° F. This patent teaches that expansion of the FEP-Fluorocarbon tubing may be accomplished by introducing a positive gas pressure into the lumen of a closed-end tube of the FEP-fluorocarbon. Seiler, Jr. *et al.* U.S. Patent No. 4,647,416 issued March 3, 1987 discloses a polytetrafluoroethylene (PTFE) tube and a method of making the tube by creating radial  
5 scores in the outer surface of unsintered PTFE tubing and either longitudinally stretching the tubing to separate the score lines into discrete ribs or subjecting the tubing to sintering temperatures to cause shrinkage of the PTFE intermediate the score lines to differentiate the score lines into ribs during the sintering process.

Tu, *et al.* disclosed a trilogy of references which disclose methods of fabricating ePTFE  
10 elastomer impregnated materials which are radially and/or longitudinally compliant. U.S. Patent No. 4,816,339 issued March 28, 1989 discloses a tubular vascular graft material made of a layer of expanded polytetrafluoroethylene (ePTFE) laminated with an ePTFE / elastomer layer and a method of making the same by preforming the graft, longitudinally expanding the graft, sintering the graft, radial expanding the graft using the elastomer matrix to permit radial  
15 expansion and compliance of the resulting graft and then wrapping or retreating the outer surface with another layer of the elastomeric material. This patent expressly teaches that standard ePTFE grafts do not hold or resist radial dilatation unless they are wrapped and if wrapped, they are non-compliant. The addition of the elastomer encapsulates the PTFE nodes and fibrils and penetrates into the microporous network of the ePTFE material. Tu, *et al.*  
20 U.S. Patent No. 5,061,276 issued October 29, 1991 is similar to the '399 Tu, *et al.* patent but discloses a graft which is made entirely of a PTFE elastomer solution admixture having inner surface distances of 25 microns and outer surface internodal distances of approximately 90 microns. The Tu, *et al.* U.S. Patent No. 5,071,609 issued December 10, 1991 discloses a graft

made by paste extrusion of a PTFE elastomer admixture, followed by expansion and contraction of the finished product either in the longitudinal or radial direction. This patent teaches that the incorporation of the elastomer is necessary to achieve the property of being expandable and contractible, *i.e.*, compliant in either the radial or longitudinal axis of the graft.

5 Yamamoto, *et al.* U.S. Patent No. 4,830,062 issued May 16, 1989 disclose radial expansion of tetrafluoroethylene tubes to impart porosity in the tube and the resulting heat shrinkability of the radial expanded tetrafluoroethylene tube. This patent does not disclose either the radial expandability of longitudinally expanded ePTFE or the heat shrinkable nature of radial expanded ePTFE.

10 Interestingly, the Primm U.S. Patent No. 4,957,669 issued September 18, 1990, discloses a method for radially expanding a tapered ribbed graft, made in accordance with the teachings of Seiler, Jr., *et al.*, U.S. Patent No. 4,647,416, by mounting the ribbed graft onto an ultrasonic horn having a generally frustroconical tapered shape, restraining the ends, and ultrasonically heating the tubing while stretching the tubing over the tapered shape of the  
15 ultrasonic horn. However, this method relies upon ultrasonic heating of the ePTFE material which increases its workability and upon the ultrasonic energy which urges the heated material into the regular tapered frustroconical shape. This method radially expands the PTFE material using the heat and ultrasonic energy as the motive force for expansion. Because the method heats the ePTFE material as it is being urged into conformation with the tapered shape of the  
20 ultrasonic horn, the ePTFE microstructure is compromised. Moreover, because of the need for the ultrasonic horn, the conformational shapes which may be formed are limited to simple



regular shapes which are capable of easy removal from the ultrasonic horn without compromising the integrity of the ePTFE material.

### **Summary of the Invention**

The fabrication of irregular-shaped, conformationally complex, medical endoprostheses from biocompatible prosthetic materials, such as ePTFE, has been difficult. Heretofore, those skilled in the art of making endoprostheses suitable for use as vein or arterial grafts, shunts, or the like, have been limited to fashioning the prosthesis of a substantially tubular structure. The surgeon has been left to adapt the tubular structure to the particular application, *e.g.*, end-to-side anastomosis of a distal bypass graft for treating peripheral arterial occlusive disease, such as by fashioning a vein cuff by, for example, making a Miller cuff or a Taylor cuff to minimize compliance mismatch between the synthetic biomaterial and the native arterial tissue. As is reflected in our related patent application, PCT International Application Serial No. PCT/US96/02715, filed February 28, 1996, entitled "Apparatus and Method for Making Flanged End-to-Side Anastomosis," we have discovered a new method of fabricating ePTFE into a flange graft having a tubular body and a flanged end section which is angularly displaced from the longitudinal axis of the graft which entails molding an ePTFE tube by radially expanding a portion of an ePTFE tube into a shaping mold so that the exterior surface of the ePTFE tube is in contact with the shaping mold surface. The present invention offers an alternative approach to forming complex conformations for endoprostheses from ePTFE in which an ePTFE tube is radially expanded to a diameter which is relatively greater than the unexpanded diameter of the ePTFE tube, the radially expanded ePTFE tube is engaged about a shaping mold, then heated which causes the radially expanded ePTFE tube to radially contract about the shaping mold, thereby forming to the external configuration of the shaping mold.

Highly constrained regions, or highly tortuous regions may require external wrapping in order to ensure close conformation with the shaping mold. In the inventive method of making an ePTFE endoprosthesis, the shaped ePTFE material has its internal surface in intimate contact with the shaping mold.

5

### **Brief Description of the Drawings**

Figure 1 is a flow diagram of the method for making shaped three-dimensional products from microporous expanded polytetrafluoroethylene in accordance with the present invention.

10 Figure 2 is a diagrammatic view illustrating the apparatus for radially expanding ePTFE showing a radially expanded ePTFE tube therein.

Figure 3 is a diagrammatic view illustrating a shaping mandrel for shaping rePTFE in accordance with the present invention showing a rePTFE tube engaged thereabout.

Figure 4 is a diagrammatic view illustrating engagement of rePTFE about a shaping mandrel.

15 Figure 5 is a diagrammatic view illustrating engagement of contracted rePTFE about a shaping mandrel.

Figure 6A is a side elevational view of a second embodiment of a shaping mandrel.

Figure 6B is a top elevational view of the second embodiment of a shaping mandrel.

20 Figure 7 is a front elevational view of a heating oven assembly and depicting a shaping mandrel and rePTFE engaged thereupon positioned in the heating oven.

Figure 8 is an end elevational view of Figure 7.

Figure 9 is a perspective view of an ePTFE tubular member with lateral branches made in accordance with the method of the present invention.

Figure 10 is a perspective, partial cut-away, view of an endoluminal stent graft made in accordance with the method of the present invention.

Figure 11 is a perspective view of a prosthetic aortic arch made in accordance with the method of the present invention.

5        Figure 12A is a perspective view of a prosthetic bifurcated graft made in accordance with the method of the present invention.

Figure 12B is a perspective view of a shaping mandrel and crimping member used to make the prosthetic bifurcated graft depicted in Figure 12B.

#### **Detailed Description of the Preferred Embodiments**

10        The method of the present invention is described in greater detail with reference to the accompanying Figures 1-8, in which like features are identified by like reference numerals. The inventive method 10 is set forth in Figure 1 by its major process steps. PTFE resin 12, preferably a high molecular weight resin such as that sold under the trademark CD 123 (ICI Chemical Company), is blended with an extrusion aid lubricant 14, preferably a mineral spirits  
15        solvent, such as that sold under the trademark ISOPAR M (Exxon Chemical Co.). It is preferable that the lubricant be present in an amount between 15- 30 wt. % of the PTFE resin, preferably between 18 and 25 wt. %. The weight percent of lubricant to PTFE resin is referred to as the "lubricant level" or "lube level." The admixture of PTFE resin and lubricant is then preformed into an extrusion billet at step 16. The extrusion billet is then extruded in a ram  
20        extruder to form tubular extrudates at step 18. The tubular extrudates are then dried at step 20 to evaporate at least a substantial quantity of lubricant present in the extrudate and then longitudinally expanded at step 22. Longitudinal expansion of the dried tubular extrudates imparts the node and fibril microstructure characteristic of ePTFE as taught by U.S. Patents

3,953,566, 4,187,390 and 4,482,516, which are hereby expressly incorporated by reference for their teaching of methods of making ePTFE tubes and films. The dried tubular extrudates are then placed into a sintering oven, while restraining the ends against longitudinal shortening, and at least partially sintered.

5           As used herein, the term "sintered" is intended to refer to the ratio of relative amorphous content of heat treated ePTFE as measured by differential scanning calorimetry wherein the amorphous content is at least 10%. Differential scanning calorimetry is a thermoanalytical method which effectively measures the difference in temperature between the sample and a reference material while both are heated simultaneously by measuring a quantum  
10 of additional heat required to maintain the sample and the reference material at a zero temperature differential. A temperature difference signal is generated when there is a  $\Delta T$  between the sample and reference. The temperature difference signal is fed into a signal amplifier which drives a separate heater which supplies additional heat equal to the  $\Delta T$  value. The DSC then measures the heat input in millicalories per second. When the sample reaches  
15 a temperature at which an endothermic process, such as a solid-solid transition, *e.g.*, phase change from crystalline to amorphous structure, occurs, the sample will not be heated as rapidly as the reference and a temperature difference appears. Conversely, when a sample reaches a temperature at which an exothermic process occurs, *e.g.*, crystallization, the sample will gain in temperature relative to the reference and a temperature difference will appear. After the  
20 onset of each temperature differential, the base line will again approach zero after the process is complete, and subsequent exothermic or endothermic events may be observed as the sample and reference are heated.

As used herein, the terms "partially sintered" or "semi-sintered" are intended to mean that the PTFE material has a crystalline conversion value between about 0.10 and 0.85, preferably 0.20 to 0.75. The crystalline conversion value is calculated using the following equation:

$$\text{Crystalline Conversion} = \frac{\Delta H_1 - \Delta H_3}{\Delta H_1 - \Delta H_2}$$

5 here  $\Delta H_1$  is the heat of fusion of the unsintered PTFE measured by differential scanning calorimetry ("DSC"),  $\Delta H_2$  is the heat of fusion of the fully sintered PTFE measured by DSC, and  $\Delta H_3$  is the heat of fusion of the semisintered PTFE measured by DSC, where an unsintered PTFE article has a crystalline conversion value of 0 and a fully sintered PTFE article has a crystalline conversion value of 1 and the ePTFE product is dimensionally stable under  
10 ambient physiological conditions.

Turning now to Figures 2-5 the various equipment used in process 10 are illustrated. A tubular ePTFE member 48, which is at least partially sintered, is co-axially engaged about a dilatation catheter 44 having an inflation balloon 46 carried thereupon. The dilatation catheter 44, inflation balloon 46 and tubular ePTFE member 48 are introduced into a  
15 constraining chamber 42. In accordance with the best mode for practicing the invention, the constraining chamber 42 has a generally tubular configuration, having a circular transverse cross-sectional shape, and has an inner diameter which is approximately 200 to 400 % greater than the outer diameter of the tubular ePTFE member 48. The constraining chamber 42 is preferably made of any suitable material which is capable of safely withstanding applied radially  
20 directed pressures in excess of the burst pressure of the inflation balloon 46. It has been found

that a plastic marketed under the trademark LEXAN by DuPont de Nemours is particularly well suited to this application due to its strength and transparency.

The tubular ePTFE member 48, inflation balloon 46, and dilatation catheter 44 are introduced into the constraining chamber 42 such that the constraining chamber 42 resides concentrically about the tubular ePTFE member 48. A positive pressure is applied through the dilatation catheter 44 and into the inflation balloon 46 which imparts a radially directed force against the luminal surface of the tubular ePTFE member. It is known in the art to employ radiopaque saline, Ringers solution or distilled water which is pumped, via a manually or mechanically actuated syringe, through the dilatation catheter 44 and into the inflation balloon 46 as the pressure source. The at least partially sintered tubular ePTFE member 48 will radially expand under the influence of the radially outwardly directed fluid pressure being exerted through the inflation balloon 46 until it is in intimate contact with and conforms to the inner surface 43 of the constraining chamber 42. It will be appreciated by those skilled in the art that various configurations of the inner surface 43 of the constraining chamber 42 may be employed to impart a radially expanded shape to the tubular ePTFE member 48. Examples of such alternative dimensional configurations for the constraining chamber 42 include regular shapes such as frustroconical, stepped, or step tapered or irregular shapes, such as bell shaped or horn shaped. Still further, the inner surface 43 of the constraining chamber 42 may have a surface configuration which includes patterns or discontinuities, such as corrugations, recesses or protrusions which will impress a pattern or discontinuity upon the outer surface of the tubular ePTFE member 48 as it is radially expanded into intimate contact with the inner surface 43 of the constraining chamber 42.

A shaping mandrel 50, such as that used to make the inventive flanged graft for end-to-side anastomosis disclosed in co-pending PCT International Application Serial No. PCT/US96/02715, filed February 28, 1996, entitled "Apparatus and Method for Making Flanged End-to-Side Anastomosis," is illustrated in Figure 3. Shaping mandrel 50 includes a generally cylindrical body section 52 and a radially flared end section 56. To form the flanged graft for end-to-side anastomosis, the radially flared end section 56 has a bell-like shape and is angularly displaced from the longitudinal axis 51 of the shaping mandrel 50. To form the flanged graft for end-to-side anastomosis, the radially flared end section 56 preferably has a toe section 58 which is angularly displaced from the longitudinal axis 51 of the shaping mandrel 50 by an angle  $\delta$  which is greater than  $90^\circ$  and less than  $180^\circ$  displaced from the longitudinal axis 51 of the shaping mandrel 50. The radially flared end section 56 also preferably has a heel section 60 which is angularly displaced from the longitudinal axis 51 of the shaping mandrel by an angle  $\theta$  which is less than  $90^\circ$  and greater than  $0^\circ$  displaced from the longitudinal axis 51 of the shaping mandrel 50. The angles  $\delta$  and  $\theta$  are measured between the longitudinal axis 51 and a line 55 extending from an outer surface of toe section 58 through the longitudinal axis 51 to the heel section 60.

Figure 4 depicts engagement of the shaping mandrel 50 concentrically within the radially expanded ePTFE 48 and covering at least a portion of the cylindrical body section 52 and the entire radially flared end section 56, including the toe section 56 and the heel section 60 of the shaping mandrel. Once the ePTFE member 48 is engaged about the shaping mandrel, the assembly is introduced into a heating oven at a temperature below the second crystalline melt point of the ePTFE member 48 and heated for a period of time sufficient to cause the ePTFE tubular member 48 to radially contract about and conform to the shaping member 50

as illustrated in Figure 5. Depending upon the configuration of the shaping member 50, especially where the flared end section 56 has a heel region 60 having an angle  $\theta$  which is less than or equal to  $45^\circ$ , to provide an external wrap of polytetrafluoroethylene tape, for example PTFE or TEFLON tape, helically wrapped about the shaping mandrel 50, particularly the flared end section 56 and tensioned thereabout to confine the ePTFE member 48 to the geometry of the flared end section 56.

Figures 6A and 6B depict an alternative embodiment of the shaping mandrel 70 as having an elongate shaft 72 passing along and defining the longitudinal axis of the shaping mandrel 70. The elongate shaft 72 has a transverse cross-sectional diameter which corresponds to the diameter of the non-flared section of the ePTFE end product desired. A generally cylindrical shaping body 74 is provided at a point along the longitudinal axis of the elongate shaft 72 and has a diameter larger than the elongate shaft 72 and corresponding to the desired final diameter of the end product. The cylindrical shaping body 74 has a beveled end section 76 which subtends an angle  $\delta$  relative to the longitudinal axis of the shaping mandrel 70. Angle  $\delta$  may assume any desired angular displacement from the longitudinal axis between a value greater than 0 and less than  $90^\circ$ , but is preferably between  $25^\circ$  and  $45^\circ$ . As with the shaping mandrel 50, it is preferable to make the shaping mandrel 70 of a material which is compatible with ePTFE and is suitable for use in manufacturing implantable medical devices, *e.g.*, stainless steel.

Figures 7 and 8 depict a heating assembly 80 for inducing radial contraction of the ePTFE member 42 into intimate contact with the configuration of the shaping mandrel 70, specifically the elongate shaft 72 and the cylindrical shaping body 74. The heating assembly



consists generally of a clam-shell oven 82 having an electrical induction heating element and ceramic insulation and openings on each opposing lateral end to permit the elongate shaft 72 to pass laterally through the clam-shell oven 82 while exposing the cylindrical shaping body 74 and the portion of the ePTFE member 42 to the heating elements within the clam-shell oven 82. Clamping members 85 and 86 are preferably provided adjacent each opposing lateral end of the clam-shell oven 82 to secure sections of the elongate shaft 72 which project from the clam-shell oven 82.

In accordance with the best mode for practicing the method of the present invention, it is preferable that the step of radially expanding the ePTFE tubular member 26 be carried out at a temperature approximating human body temperature, i.e., be between about 35 - 45°C. This may be accomplished by radially expanding in heated air or in a heated water bath. Similarly, it is preferable that the heat shrink step 32 be performed at a temperature above the first crystalline melt point of PTFE, but below the second crystalline melt point of PTFE, preferably between 327 to 340°C and that the ePTFE tubular member and the shaping mandrel be subject to heating for between 5 minutes and 10 minutes dwell time in the heating oven, preferably for about 8 minutes. Additionally, prior to heating the ePTFE tubular member during the heat shrink step 32, it is desirable to tightly wrap the ePTFE tubular member about the flared or tapered end section of the shaping mandrel 50, loosely wrap the ePTFE tubular member which is on the elongate shaft of the shaping mandrel and then clamp the ePTFE tubular member sections which project outside the oven to guard against longitudinal contraction during heating.

It will be appreciated that a wide variety of tubular ePTFE articles may be made by the method of the present invention. By altering the three-dimensional conformation of the shaping mandrel, and adding post-processing steps, such as trimming to achieve the final product configuration, the present invention may be adapted to produce a wide variety of tubular medical prosthetic devices.

Examples of such other tubular medical prosthetic devices are illustrated in Figures 9-12 in the accompanying drawings. Briefly, Figure 9 depicts a branched vascular graft 100 which consists of an ePTFE tubular body 102 and has a plurality of smaller branch conduits 103 and 104 projecting laterally outward from the tubular body 102. The branch conduits 103 and 104 are positioned about the circumference of the tubular body 102 at a position which is anatomically matched with a patient's corresponding branch conduits. For example, where the ePTFE tubular body 102 is fashioned as an arterial implant in the descending aorta, the plurality of branch conduits 103 and 104 may be positioned to correspond to the anatomic position of the patient's renal arteries to the endogenous renal arteries may be anastomosed to the branch conduits 103 and 104 projecting from the tubular body 102.

Figure 10 illustrates an endoluminal stent-graft device which is fashioned in accordance with the above-described inventive method, except that an endoluminal stent, such as a PALMAZ stent (Johnson & Johnson Interventional Systems, Inc. Warren, New Jersey), a GIANTURCO stent (Cook Medical Corp., Indianapolis, Indiana), a WALLSTENT (Schneider, USA), or a NITINOL stent is substituted from the shaping mandrel and the radially expanded ePTFE tubular member 112 is radially contracted about the stent 114.

Figure 11 illustrates a prosthetic aortic arch 120 consisting of an ePTFE aortic prosthesis 122 having a central lumen 123 and a plurality of branch arterial prosthetic limbs 124, 126 projecting outwardly from the crest of the aortic arch prosthesis 122. The ePTFE aortic prosthesis is fashioned in accordance with the above-described inventive method, except  
5 that the shaping mandrel is configured in a C-shape and has a plurality of projections emanating from a position along the length of the shaping mandrel which form the branch arterial prosthetic limbs 124, 126 when the radially expanded ePTFE is radially contracted about the shaping mandrel.

10 Finally, a bifurcated graft 130, illustrated in Figure 12B, may be formed in accordance with the above-described inventive method. As with any conventional bifurcated graft prosthesis useful at the femoral branch of the descending aorta, the inventive bifurcated graft 130 consists of a Y-shaped tubular member having a main body portion 132 and a main lumen 131 open to a proximal end of the main body portion 132. The main body portion 132 is  
15 bifurcated at a distal end thereof into a plurality of bifurcated tubular members 134, 136, each of the plurality of bifurcated tubular members 134, 136 has an associated bifurcated lumen 135, 137 therein. The bifurcated lumina 135, 137 communicate with the main lumen 131 to conduct a fluid flow, such as blood, through the main lumen 131 and into and through the bifurcated lumina 135, 137. It will be appreciated that the bifurcated graft 130 is not limited to having  
20 two bifurcated lumina 135, 137, but may include more than two bifurcations to correspond with a branched anatomical structure having more than two bifurcations.

The bifurcated graft 130 may be made in accordance with the present invention utilizing the shaping mandrel 140 and crimping member 144 illustrated in Figure 12B. A partially

sintered ePTFE tubular member 142 is radially expanded as described above. A Y-shaped shaping mandrel consisting of a cylindrical main body portion 146 and a plurality of bifurcated leg sections 148, 149 which project from one end of the cylindrical main body portion 146 and are angularly displaced away the longitudinal axis of the shaping member. It is preferable that at least one of the bifurcated leg sections 148, 149 be removably coupled to the cylindrical main body portion 146, such as by a threaded coupling 150, to facilitate removal of the shaping mandrel from the finished bifurcated graft 130.

The radially expanded ePTFE tubular member 142 is engaged concentrically about the Y-shaped shaping mandrel as described above. A crimping member 144, consisting of a pair of generally triangular head members 145, 147 which are co-planar with and superimposable upon one another. A handle member 151 projects outwardly from each of the generally triangular head members 145, 147 and forms a junction at an end opposing the triangular head members 147, 149 (not shown) which permits the crimping member 144 to function in a tong-like or forceps-like manner. It is preferable that either the handle member 151 or the generally triangular head members 145, 147 have a means for applying a positive pressure between the generally triangular head members 147, 149 such that opposing planar surfaces of the generally triangular head members 147, 149 are capable of being brought into intimate contact with one another or into intimate contact with a planar surface interposed between the generally triangular head members 147, 149.

The crimping member 144 is applied over a webbed section of radially expanded ePTFE which subtends the bifurcation of the shaping mandrel 148 and the ePTFE unsupported between the bifurcated leg members 148, 149 is crimped between and in intimate contact with

the opposing generally triangular shaped head members 145, 147. A positive pressure is applied to the generally triangular shaped head members 145, 147 to cause the adjacent ePTFE surfaces to come into intimate contact with one another under pressure.

5 The entire assembly is then heated to a temperature below the second crystalline melt point of PTFE to cause the ePTFE to radially contract over and assume the shape of the shaping mandrel 140. It will be appreciated that by engaging the ePTFE subtending the space between the bifurcated leg members 148, 149, generally tubular leg sections 155, 157 in the ePTFE are formed.

10 The entire assembly, including the ePTFE 142, the shaping mandrel 140 and the crimping member 144 are then wrapped with PTFE tape to secure the contracted ePTFE onto the shaping mandrel and secure the crimping member 144 in its position relative to the shaping mandrel 140. The wrapped assembly is then introduced into the sintering oven to sinter the ePTFE. After removal from the sintering oven, the assembly is allowed to cool. The PTFE tape is removed from the assembly, and at least one of the bifurcated leg sections 148, 149 are  
15 decoupled from the main body portion 146 of the shaping mandrel and crimping member 144 is removed from the sintered ePTFE shaped graft 142. The sintered ePTFE shaped graft 142 is removed from the shaping mandrel 140 and the ePTFE web subtending the space between the tubular leg sections 155, 157 of the ePTFE graft is trimmed away leaving a seam formed by overlapping and joined sections of the ePTFE tubular member 142.

**What is Claimed is:**

1                   1.           A method for shaping expanded polytetrafluoroethylene tubes into a  
2 shaped three-dimensional article, comprising the steps of:

3                   (a)       extruding an admixture of polytetrafluoroethylene resin and lubricant  
4 into a tubular extrudate;

5                   (b)       drying the tubular extrudate of at least a major fraction of lubricant;

6                   (c)       longitudinally expanding the tubular extrudate to impart a  
7 polytetrafluoroethylene microstructure having a plurality of nodes interconnected by fibrils;

8                   (d)       at least partially sintering the longitudinally expanded tubular extrudate  
9 to impart a dimensional stability in the tubular extrudate greater than the unsintered tubular  
10 extrudate;

11                  (d)       radially expanding the at least partially sintered tubular extrudate to a  
12 diameter greater than that of the tubular extrudate.

13                  (e)       engaging the radially expanded at least partially sintered tubular  
14 extrudate circumferentially about a shaping mandrel, the shaping mandrel having a three-  
15 dimensional conformation; and

16                  (f)       heating the shaping mandrel and the at least partially sintered tubular  
17 extrudate, thereby shrinking the partially sintered tubular extrudate into intimate contact with  
18 the shaping mandrel thereby shaping the partially sintered tubular extrudate about the shaping  
19 mandrel.

2. The method according to Claim 1, wherein said step of drying and at least partially sintering the tubular extrudate further comprises the step of fully sintering the tubular extrudate such that the extrudate has a crystalline conversion value of 1.

3. The method according to Claim 1, wherein the step of at least partially sintering the tubular extrudate further comprises the step of heating the tubular extrudate at a temperature above the crystalline melt point of PTFE for a period of time to semisinter the tubular extrudate such that it has a crystalline conversion value between 0.10 and 0.85.

4. The method according to Claim 3, further including the step of fully sintering the semisintered the tubular extrudate after the step of shrinking the tubular extrudate into intimate contact with the shaping mandrel.

5. The method according to Claim 1, wherein the step of heating further comprises the step of exposing the shaping mandrel and the at least partially sintered tubular extrudate to a temperature below the crystalline melt point of polytetrafluoroethylene and above an ambient temperature at which the step of radially expanding is conducted.

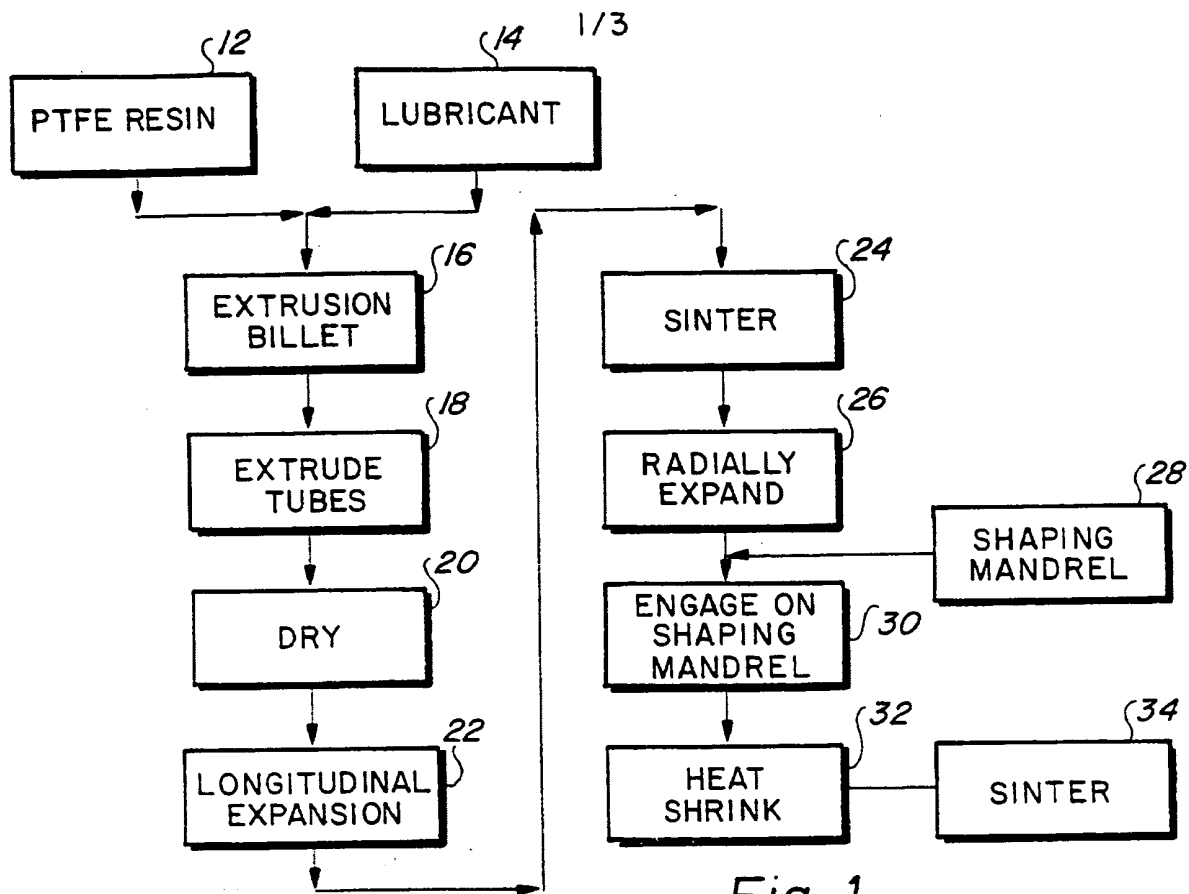


Fig. 1

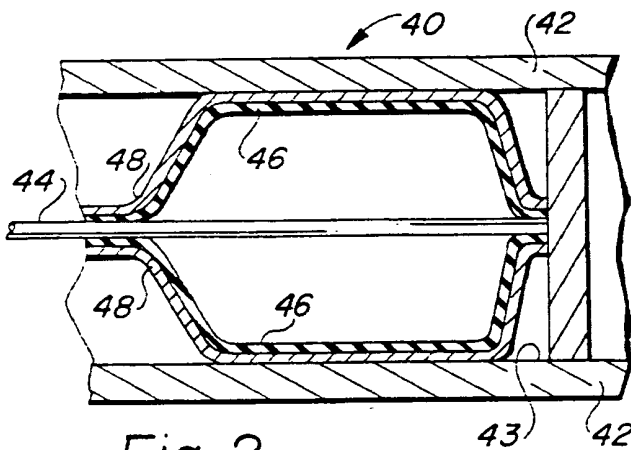


Fig. 2

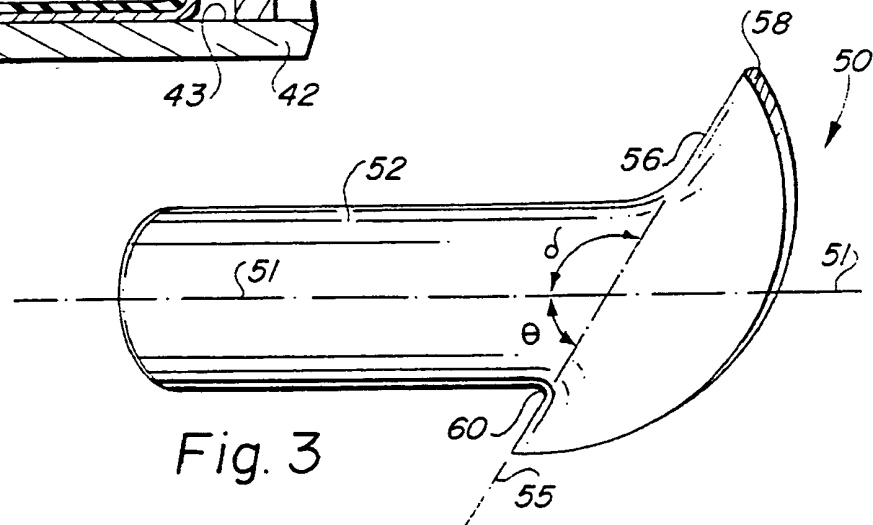


Fig. 3



2 / 3

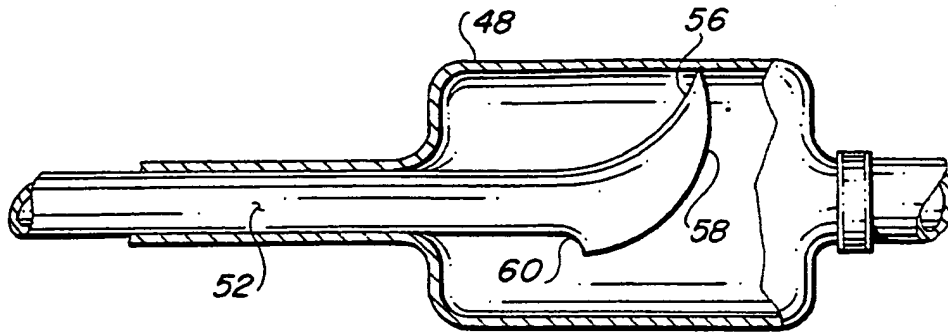


Fig. 4

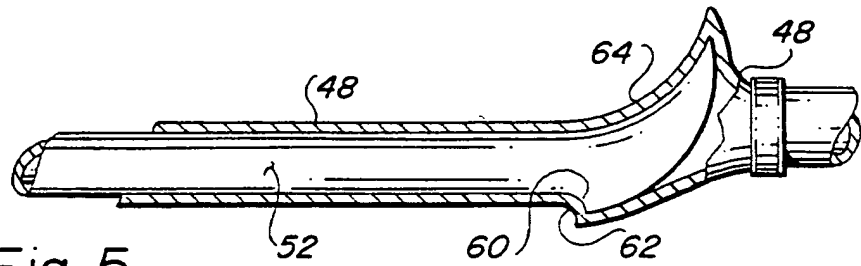


Fig. 5

Fig. 8

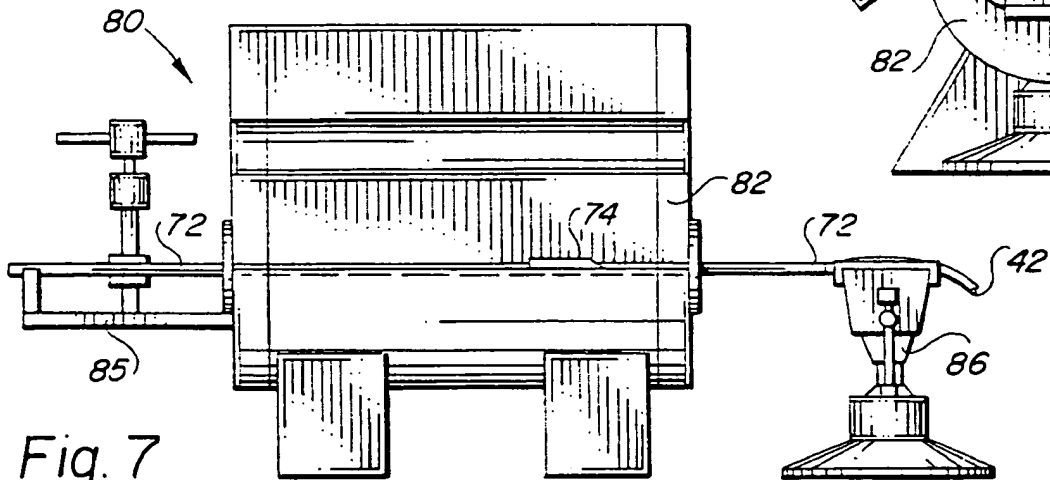
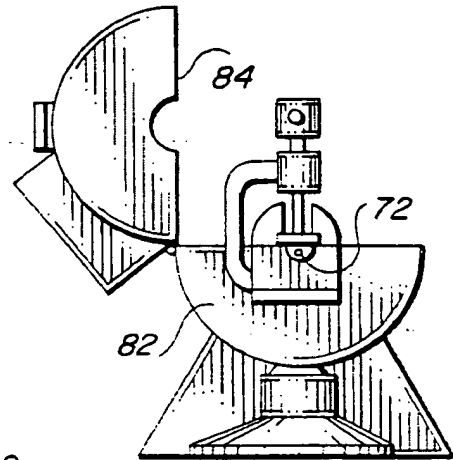


Fig. 7

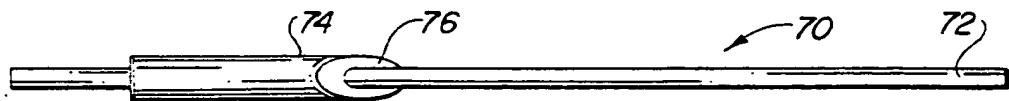


Fig. 6B

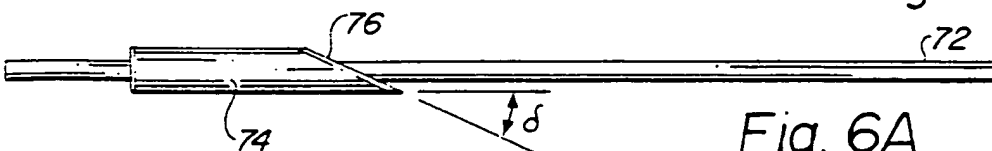


Fig. 6A

3/3

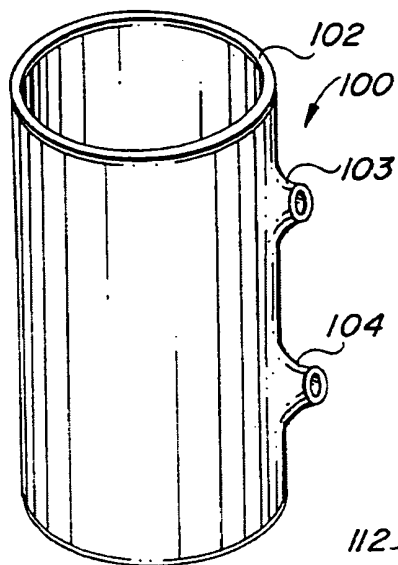


Fig. 9

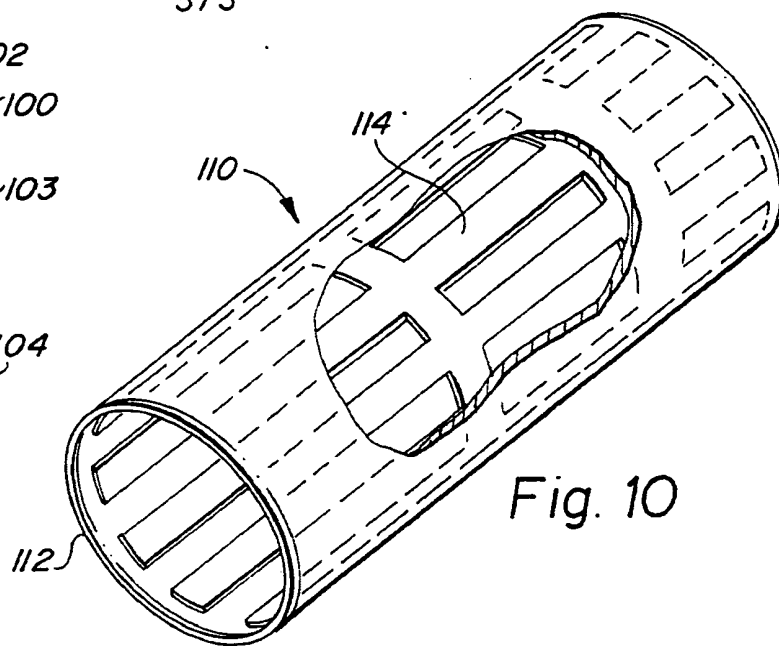


Fig. 10

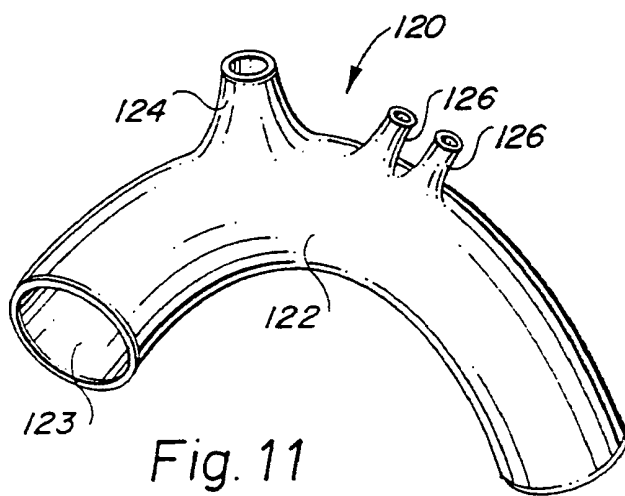


Fig. 11

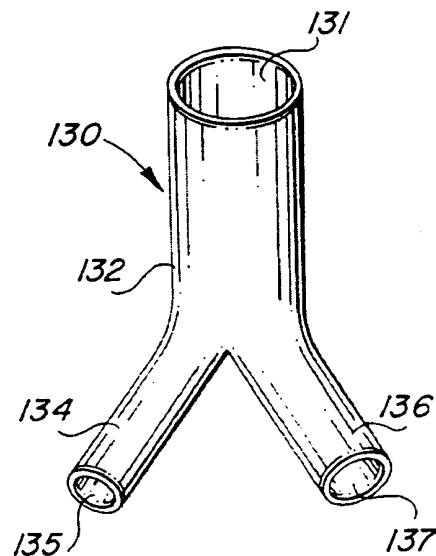


Fig. 12A

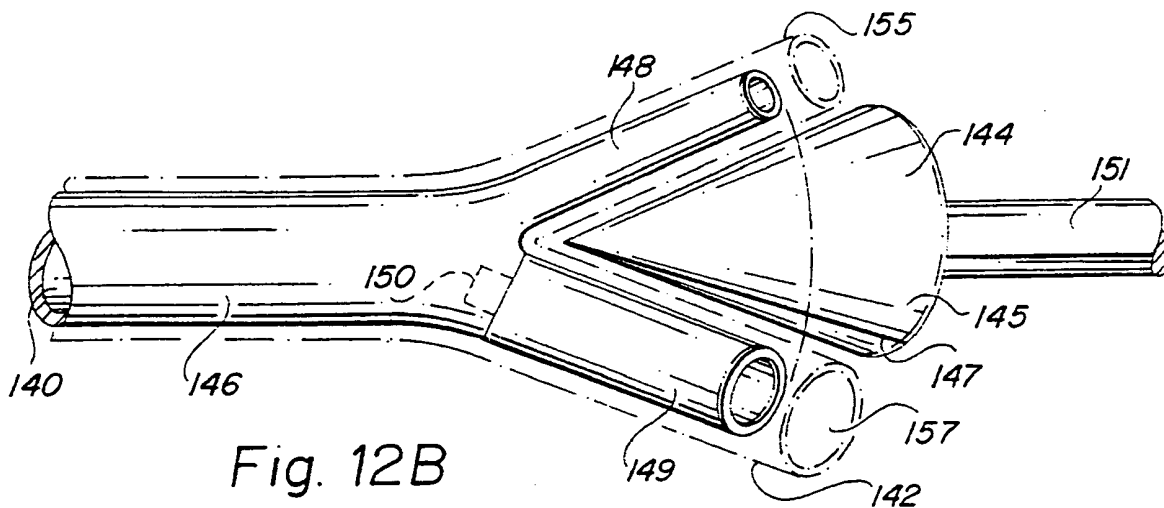


Fig. 12B

**A. CLASSIFICATION OF SUBJECT MATTER**

IPC 6 B29C61/02 B29C55/26 A61F2/06

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 B29C A61F A61L

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	WO 96 33066 A (BAXTER INT) 24 October 1996 see page 11, line 9 - page 14, line 33 ----	1-5
A	WO 96 28115 A (IMPRA INC) 19 September 1996 see claims 20,21; examples -----	

☐ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.**\* Special categories of cited documents :**

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&amp;" document member of the same patent family

Date of the actual completion of the international search

28 May 1998

Date of mailing of the international search report

10/06/1998

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2  
NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

Attalla, G

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
WO 9633066	A	24-10-1996	US 5641373 A	24-06-1997
			AU 5545796 A	07-11-1996
			EP 0821648 A	04-02-1998
<hr/>				
WO 9628115	A	19-09-1996	US 5749880 A	12-05-1998
			CA 2215027 A	19-09-1996
			EP 0814729 A	07-01-1998
<hr/>				